

### **§ 73.11 Security.**

(a) An entity must develop and implement a security plan establishing policy and procedures that ensure the security of areas containing select agents and toxins. The security plan must be based on a systematic approach in which threats are defined, vulnerabilities are examined, and risks associated with those vulnerabilities are mitigated with a security systems approach.

(b) The plan must:

(1) Describe inventory control procedures, minimal education and experience criteria for those individuals with access to select agents or toxins, physical security, and cyber security;

(2) Contain provisions for routine cleaning, maintenance, and repairs; provisions for training personnel in security procedures; provisions for securing the area (e.g., card access, key pads, locks) and protocols for changing access numbers or locks following staff changes;

(3) Describe procedures for loss or compromise of keys, passwords, combinations, etc.;

(4) Contain procedures for reporting suspicious persons or activities, loss or theft of listed agents or toxins, release of listed agents or toxins, or alteration of inventory records;

(5) Contain provisions for the control of access to containers where listed agents and toxins are stored; and procedures for reporting and removing unauthorized persons;

(6) Contain provisions for ensuring that all individuals with access, including workers and visitors, understand security requirements and are trained and equipped to follow established procedures;

(7) Establish procedures for reporting and removing unauthorized persons; and

(8) Establish procedures for securing the area when individuals approved under § 73.8 are not present (e.g., card access system, key pads, locks), including protocols for changing access numbers or locks following staff changes.

(c) The security plan must be reviewed by the RO at least annually and after any incident.

(d) With respect to areas containing select agents and toxins, the entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security as the provisions below:

(1) Allow unescorted access only to individuals who have been approved under § 73.8 and who are performing a specifically authorized function during hours required to perform the defined job (including delivery to an outside shipping agent for transportation in commerce);

(2) Allow individuals not approved under § 73.8 to conduct routine cleaning, maintenance, repairs, and other non-laboratory functions only when escorted and continually monitored by individuals approved under § 73.8;

(3) Provide for the control of access to containers where select agents and toxins are stored by requiring freezers, refrigerators, cabinets, and other containers where stocks of select agents and toxins are stored to be locked (e.g., card access system, lock boxes) when they are not in the direct view of approved staff, and by using other monitoring measures as needed, such as video surveillance;

(4) Require the inspection of all packages upon entry to and exit from the area;

(5) Establish a protocol for intra-entity transfers, including provisions for ensuring that the packaging, and movement from a laboratory to another laboratory or from a laboratory to a shipping place, is conducted under the supervision of an individual approved under § 73.8;

(6) Require that each approved individual under 73.8 does not share with any other person, his or her unique means (e.g., keycards or passwords) of accessing the area or select

agent or toxin;

(7) Require that each individual approved under § 73.8 report any of the following immediately to the Responsible Official:

- (i) Any loss or compromise of their keys, passwords, combinations, etc.;
  - (ii) Any suspicious persons or activities;
  - (iii) Any loss or theft of select agents or toxins;
  - (iv) Any release of select agents or toxins; and
  - (v) Any sign that inventory and use records of select agents or toxins have been altered or otherwise compromised.
- (e) The entity must separate areas where select agents and toxins are stored or used from the public areas of the buildings.
- (f) Upon termination of the use, a select agent or toxin must be
- (1) Securely stored in accordance with the requirements of this section;
  - (2) Transferred to another registered facility in accordance with § 73.14; or
  - (3) Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.